REMARKS

Claims 1-3 and 7-27 are pending in this application. Claims 1-3 and 7-15 have been withdrawn from consideration. Claims 16-27 have been canceled without prejudice or disclaimer. Claims 28-39 have been newly added.

Applicants thank the Examiner for indicating that claims 18 and 26 are free of the prior art and would be allowable if they were rewritten in independent form including all of the limitations of the base claim and any intervening claims. Accordingly, claim 18 has been rewritten in independent form as new claim 28. New claims 30, 32, 34, 36, and 38, are all directly or indirectly dependent on new claim 28.

New claim 29 corresponds to canceled claim 19 written in independent form to include all of the limitations of base claim 16. New claims 31, 33, 35, 37, and 39, are all directly or indirectly dependent on new claim 29.

Claims 28-39 find support throughout the specification, Examples, and claims, as originally filed. No new matter has been added.

In view of the remarks set forth herein, further and favorable consideration is respectfully requested.

I. At page 3 of the Official Action, claims 16-17, 19-21, 23-25, and 27, have been rejected under 35 USC § 102 (b), as being anticipated by Chaudhari et al.

The Examiner asserts that the Chaudhari *et al.* reference discloses that splice variants of their disclosed receptor are possible because multiple promoters may yield mRNA's with distinct 5' exons. The Examiner points to page 118, last paragraph of the left column, in support of the foregoing. The Examiner states that therefore, one can identify

other variant receptors. The Examiner states that they explicitly do not teach expression of variants in rat small and large intestine, but that the skilled artisan would have analyzed tissue expression of various variants in different tissues and species for pharmaceutical applications. The Examiner states that Chaudhari *et al.* teach hybridization of nucleic acids for detecting message expression in various tissues and that they disclose a glutamate receptor variant comprising a transmembrane, an intracellular domain common to type 4 metabotropic receptor, a shorter receptor than a type 4 metabotropic receptor, and a method of expressing the receptor in CHO cells. The Examiner appears to conclude that Chaudhari *et al.* thus *inherently* meets the limitations of the rejected claims.

Canceled claims 16 and 19 correspond to new claim 29. New claim 29 is directed to an isolated DNA molecule. Canceled claim 17 corresponds to new claim 31and recites that the protein is expressed in rat small and large intestine. Canceled claims 20 and 21 correspond to new claims 33 and 35, respectively. New claims 33 and 35 are directed to a cell. Canceled claims 25 and 27 correspond to new claims 37 and 39, respectively. New claims 37 and 39 are directed to a method of producing glutamic acid receptor protein.

In view of the following, this rejection is respectfully traversed.

Anticipation under 35 USC § 102 requires that a single prior art reference teach each and every limitation of the claimed invention and enable one skilled in the art to make the anticipating subject matter. *See PPG Indus., Inc. v. Guardian Indus. Corp.,* 75 F.3d 1558 (Fed. Cir. 1996).

"For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art...The reference must describe the applicant's claimed invention sufficiently to have placed a

person of ordinary skill in the field of the invention in possession of it." *See In re Spada,* 911 F.2d 705 (Fed. Cir. 1990). Although the disclosure requirement presupposes the knowledge of one skilled in the art, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. *Id.*

"Summary judgment of inherency anticipation was improper because of a material fact issue whether a prior art reference's process necessarily produced the claimed invention's features." *See Continental Can Company USA, Inc. v. Monsanto Co.,* 948 F.2d 1264 (Fed. Cir. 1991). "Consistent with the law of inherent anticipation, an inherent property must necessarily be present in the invention described by the count, and it must be so recognized by persons of ordinary skill in the art." *Id.* "The mere fact that a certain thing may result from a given set of circumstances is insufficient to prove anticipation." *See Electro Medical Systems, S.A. v. Cooper Life Sciences, Inc.,* 34 F.3d 1048 (Fed. Cir. 1994).

In *Glaxo Inc. v. Novopharm Ltd.,* 52 F.3d 1043 (Fed. Cir. 1995), the court held that the patent claim in suit was not inherently anticipated where the prior art process produced alternate forms. More specifically, the Glaxo court held that Form 2 of ranitidine was not "inherently and necessarily" produced in Example 32 of Glaxo's patent. The question is whether the missing element "is necessarily present in the thing described in the reference and that it would be so recognized." *See Rosco, Inc. v. Mirror Lite Co.,* 304 F.3d 1373 (Fed. Cir. 2002). Regarding recognition, the question is whether one skilled in the art would read the prior art reference as inherently disclosing the invention. *Id.*

"Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."

See In re Oelrich, 666 F.2d 578, 581 (CCPA 1981). "Occasional results are not inherent." *See Mehl/Biophile International Corp. v. Milgraum,* 192 F.3d 1362 (Fed. Cir. 1999). "A reference includes an inherent characteristic if that characteristic is the natural result flowing from the reference's explicitly explicated limitations." *See Continental Can Company USA, Inc., supra.*

Claims 29 and 33:

The Examiner appears to assert that Chaudhari *et al.* inherently meets the limitations of claims 16, 19, and 23 (new claims 29 and 33).

Present claim 29 recites:

> An isolated DNA molecule that encodes a glutamic acid receptor protein and hybridizes to a DNA molecule having a nucleotide sequence represented by SEQ ID NO: 6 under conditions of 60°C, 1 x SSC, and 0.1 % SDS, and
>
> wherein the glutamic acid receptor protein comprises
>
> a transmembrane domain and an intracellular domain common to those of brain type 4 metabotropic glutamic acid receptor protein, and
>
> an extracellular domain that is about 316 or 327 amino acid residues shorter than the extracellular domain of the brain type 4 metabotropic glutamic acid receptor protein.

The DNA molecule of claim 29 hybridizes to a DNA molecule having a nucleotide sequence represented by SEQ ID NO: 6 under conditions of 60°C, 1 x SSC, and 0.1 % SDS. As ***admitted*** by the Examiner at page 3, lines 18-19, of the Official Action, Chaudhari *et al.* ***does not*** disclose a DNA molecule having a nucleotide sequence

represented by SEQ ID NO: 6. The Examiner states at page 3, lines 19-21, to page 4, line 1, that "Chaudhari *et al.* disclose that splice variants of their disclosed receptor are ***possible*** ... Therefore one can identify other variant receptors." (emphasis added). Accordingly, the Examiner admits that the identification of other variant receptors is, at best, "possible."

At most, the process disclosed in Chaudhari *et al.* may ***possibly occasionally permit*** the identification of variants that might ***possibly*** include the claimed variant. However, Applicants note that inherent anticipation requires that the claimed features are ***necessarily*** produced by the prior art process or are ***necessarily*** present in the prior art product or structure. *See In re Oelrich,* 666 F.2d 578, 581 (CCPA 1981), and *Mehl/Biophile International Corp. v. Milgraum,* 192 F.3d 1362 (Fed. Cir. 1999).

In fact, because Chaudhari *et al.* allegedly teaches producing taste variants but does not teach the claimed variant, the Chaudhari *et al.* reference itself establishes that the described process does ***not necessarily*** produce the claimed variant of SEQ ID NO: 6.

In view of the foregoing, it is submitted that Chaudhari *et al.* does not teach, either expressly or inherently, each and every element claimed in claims 29 and 33, as required for anticipation under 35 USC § 102 (b). Accordingly, the Examiner is respectfully requested to withdraw this rejection as to claims 29 and 33.

Claim 31 and 35:

The Examiner appears to assert that Chaudhari *et al.* inherently meets the limitations of claims 21 and 25 (new claims 31 and 35).

The Examiner, at page 4 of the Official Action, states that Chaudhari *et al.* "do not teach expression of variants in rat small and large intestine. However, one skill in the art would have analyzed tissue expression of various variants in different tissues and species for pharmaceutical applications."

New claim 31recites that the protein is expressed in rat small and large intestine. The Examiner appears to assert that not only does Chaudhari *et al.* inherently teach the presently claimed mGluR4 variant, but also inherently teaches its expression in rat small and large intestine. Chaudhari *et al.* ***does not*** teach, inherently or otherwise, expression of ***any*** mGluR4 variant in a rat. Chaudhari *et al.* ***does not*** teach, inherently or otherwise, expression of ***any*** mGluR4 variant in a rat small and large intestine, let alone the presently claimed variant having the claimed sequence or a DNA molecule hybridizable thereto.

Rather, Chaudhari *et al.* describes expression of taste-mGluR4 variants ***only*** in CHO cells transfected with clones of taste-mGluR4. That is, Chaudhari *et al.* does not describe a rat model of expression of taste-mGluR4 variants, let alone describe expression in the small and large intestine of such a rat model. *See* Chaudhari *et al.* at page 116, right hand column; and page 117. Accordingly, it is impossible for Chaudhari *et al.* to inherently anticipate claims 31 and 35 because the process of Chaudhari *et al.* including transfection of CHO cells and expression in CHO cells can ***never*** result in expression of the claimed variant in rat, let alone in the small and large intestine of a rat.

In view of the foregoing, it is submitted that Chaudhari *et al.* does not teach, either expressly or inherently, each and every element claimed in claims 31 and 35, as required for anticipation under 35 USC § 102 (b). Accordingly, the Examiner is respectfully requested to withdraw this rejection as to claims 31 and 35.

Claim 37:

The Examiner appears to assert that Chaudhari *et al.* inherently meets the limitations of claims 24 and 27 (new claims 37).

Claim 37 is directed to a method of producing glutamic acid receptor protein or a cell comprising the glutamic acid receptor protein, comprising cultivating a cell transformed with a DNA molecule encoding the glutamic acid receptor protein of claim 29 in an expressible form, in a medium to produce the glutamic acid receptor protein.

Claim 37 recites a DNA molecule encoding the glutamic acid receptor protein of claim 29. As discussed above, Chaudhari *et al.* does not teach, either expressly or inherently, the isolated DNA molecule claimed in claim 29. Accordingly, Chaudhari *et al.* can not, either expressly or inherently, teach a method employing the isolated DNA molecule of present claim 29.

In view of the foregoing, it is submitted that Chaudhari *et al.* does not teach, either expressly or inherently, each and every element claimed in claims 37 and 39, as required for anticipation under 35 USC § 102 (b). Accordingly, the Examiner is respectfully requested to withdraw this rejection as to claims 37 and 39.

Claim 39:

The Examiner appears to assert that Chaudhari *et al.* inherently meets the limitations of claim 25 (new claim 39).

Claim 39 is directed to a method of producing glutamic acid receptor protein or a cell comprising the glutamic acid receptor protein, comprising cultivating a cell transformed with a DNA molecule encoding the glutamic acid receptor protein of claim 31

in an expressible form, in a medium to produce the glutamic acid receptor protein. Claim 31 recites expression in rat small and large intestine. Again, the Examiner admits that Chaudhari *et al.* does not teach expression of taste variants in rat small and large intestine. Please see the above discussions with regard to present claims 31 and 35.

Claim 39 recites a DNA molecule encoding the glutamic acid receptor protein of claim 31. As discussed above, Chaudhari *et al.* does not teach, either expressly or inherently, the isolated DNA molecule claimed in claim 31 nor expression in rat small and large intestine. Accordingly, Chaudhari *et al.* can not, either expressly or inherently, teach a method employing the isolated DNA molecule of present claim 31.

In view of the foregoing, it is submitted that Chaudhari *et al.* does not teach, either expressly or inherently, each and every element claimed in claim 39, as required for anticipation under 35 USC § 102 (b). Accordingly, the Examiner is respectfully requested to withdraw this rejection as to claim 39.

In addition, Applicant's submit that, assuming *arguendo,* Chaudhari *et al.* suggests splice variants which are shorter than a type 4 metabotropic receptor, Chaudhari *et al.* does not disclose a variant which is about 316 or 327 amino acids shorter than the normal brain type 4 metabotropic receptor. Furthermore, as can be seen from the sequence alignment which was submitted on October 11, 2005, responsive to the first Official Action, the N-terminal sequence of the brain mGluR4 variant is completely different from the N-terminal sequence of the taste-mGluR4 of Chaudhari *et al.* Please note that the N-terminal sequence consisting of 14 amino acid residues of the mGluR4 variant of the present invention is unique and is not contained in both normal brain mGluR4 and the taste-

mGluR4 of Chaudhari *et al.* Thus, the mGluR4 variant of the present invention would ***not*** be produced using the multiple promoters disclosed by Chaudhari *et al.*

In view of the above, it is submitted that Chaudhari *et al.* does not teach, either expressly or inherently, each and every element of claims 16-17, 19-21, 23-25, and 27, as required for anticipation under 35 USC § 102 (b). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

II. At page 4 of the Official Action, claims 16-17, 19-21, 23-25, and 27, have been rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement.

The Examiner asserts that the rejected claims fail to comply with the written description requirement.

In view of the remarks set forth herein, this rejection is respectfully traversed.

Claims 16-17, 19-21, 23-25, and 27, have been canceled without prejudice or disclaimer. Claims 29, 31, 33, 35, 37, and 39, have been newly added and correspond to the canceled claims as discussed above.

The written description requirement is satisfied if the disclosure as originall filed conveys to those skilled in the art that the applicant had invented the sumbject matter later claimed. *See In re Kaslow,* 707 F.2d 1366. Identical description is not required. *Id.*

The PTO guidelines set forth that the written description requirement can be met by showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, for example, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combinationof such characteristics.

See Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316 (Fed. Cir. 2002). The *Enzo Biochem* court held that "Thus, under the Guidelines, the written description requirement could be met for all of the claims of the patent if the functional characteristic, i.e., of preferential binding, were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." *Id.*

Canceled claims 16 and 19 correspond to new claim 29. New claim 29 recites an isolated DNA molecule that encodes a glutamic acid receptor protein and is hybridizable with a DNA molecule having a nucleotide sequence represented by SEQ ID NO: 6 under conditions of 60°C, 1 x SSC, and 0.1 % SDS, wherein the glutamic acid receptor protein comprises a transmembrane domain and an intracellular domain common to those of brain type 4 metabotropic glutamic acid receptor protein, and an extracellular domain that is about 316 or 327 amino acid residues shorter than the extracellular domain of the brain type 4 metabotropic glutamic acid receptor protein. Claims 31, 33, 35, 37, and 39, are directly or indirectly dependent on claim 29.

The present specification clearly describes SEQ ID NO: 6. The claims are directed to an isolated DNA molecule that encodes a glutamic acid receptor protein and is hybridizable with a DNA molecule having a nucleotide sequence represented by SEQ ID NO: 6 under conditions of 60°C, 1 x SSC, and 0.1 % SDS. The claimed isolated DNA molecules are described by their ability to hybridize to structures having a sequence represented by SEQ ID NO: 6.

In addition, the specification clearly describes identifying characteristics the the claimed DNA molecule and the protein encoded by the DNA molecule. For example, the specification describes SEQ ID NO: 6; other physical and/or chemical properties, for

example, the protein comprises a transmembrane domain and an intracellular domain common to those of brain type 4 metabotropic glutamic acid receptor protein, and an extracellular domain that is about 316 or 327 amino acid residues shorter than the extracellular domain of the brain type 4 metabotropic glutamic acid receptor protein, and the glutamic acid receptor is a glutamic acid sensor in the digestive tract; functional characteristics, for example, the isolated DNA molecule is hybridizable with a DNA molecule having a nucleotide sequence represented by SEQ ID NO: 6 under conditions of 60°C, 1 x SSC, and 0.1 % SDS, as well as combinations of such characteristics.

In view of the above, it is submitted that the Specification clearly conveys to the skilled artisan that the Applicants had invented the subject matter claimed in claims 29, 31, 33, 35, 37, and 39. Thus, it is submitted that these claims are in full compliance with the written description requirement of 35 USC § 112, first paragraph. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

III. At page 4 of the Official Action, claims 16-17, 19-21, 23-25, and 27, have been rejected under 35 USC § 112, first paragraph, as not enabled.

The Examiner asserts that the rejected claims are not directed to a specific mGluR4, bur rather are directed to any brain type 4 glutamic acid receptor protein that has a transmembrane domain, an intracellular domain common to mGluR4, and an extracellular domain shorter by about 316 or 327 amino acids than mGluR4.

Claims 16-17, 19-21, 23-25, and 27, have been canceled without prejudice or disclaimer. Claims 29, 31, 33, 35, 37, and 39, have been newly added and correspond to the canceled claims as discussed above.

A patent must contain a description that enables one skilled in the art to make and use the claimed invention. *See Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569 (Fed. Cir. 1984). An inventor need not, however, explain every detail since he is speaking to those skilled in the art. *See In re Howarth,* 654 F.2d 103 (CCPA 1981). Enablement is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.,* 802 F.2d 1367 (Fed. Cir. 1986), *cert. denied,* 480 US 947 (1987). The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine. *See Johns Hopkins University v. Cellpro, Inc.,* 152 F.3d 1342 (Fed. Cir. 1998).

New claim 29 has been written to recite an isolated DNA molecule that encodes a glutamic acid receptor protein and is hybridizable with a DNA molecule having a nucleotide sequence represented by SEQ ID NO: 6 under conditions of 60°C, 1 x SSC, and 0.1 % SDS, wherein the glutamic acid receptor protein comprises a transmembrane domain and an intracellular domain common to those of brain type 4 metabotropic glutamic acid receptor protein, and an extracellular domain that is about 316 or 327 amino acid residues shorter than the extracellular domain of the brain type 4 metabotropic glutamic acid receptor protein.

Accordingly, claim 29 is not directed to "any brain type 4 glutamic acid receptor protein ...." Rather, claim 29 encompasses only those isolated DNA molecules that encode a glutamic acid receptor protein comprising the recited domains ***and*** are hybridizable with a DNA molecule having a nucleotide sequence represented by SEQ ID NO: 6 under conditions of 60°C, 1 x SSC, and 0.1 % SDS.

Further, the determination of whether or not an isolated DNA molecule that encodes a glutamic acid receptor protein, is hybridizable with a DNA molecule having a nucleotide sequence represented by SEQ ID NO: 6 under conditions of 60°C, 1 x SSC, and 0.1 % SDS, is merely routine. In addition, such determination is well within the knowledge of the skilled artisan and can be readily accomplished without undue experimentation.

The present specification provides ample guidance to the skilled artisan. The specification discloses how to make and use the invention of claims 29, 31, 33, 35, 37, and 39, at page 14, last paragraph through page 22, the Examples, and the claims as originally filed.

In view of the above, it is submitted that the Specification clearly enables the skilled artisan to make and use the full scope of the invention claimed in claims 29, 31, 33, 35, 37, and 39, without undue experimentation. Thus, it is submitted that these claims are in full compliance with the enablement requirement of 35 USC § 112, first paragraph. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

In view of the foregoing, Applicant submits that the pending claims are in condition for allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicant petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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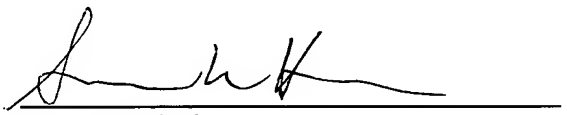

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